Remarks

Applicants thank Examiners Huynh and Chan for their courtesy during the helpful interview held June 24, 2003.

The Amendments

Several amendments have been made to claim 1. The amendments do not add new matter and do not require a new search. The amendments were not made earlier because Applicants believed their arguments were sufficient to overcome the rejections. Each of these amendments was discussed at the June 24 interview. Applicants respectfully request that the amendments be entered.

First, claim 1 now recites desensitizing a human rather than an individual. Use of methods of the invention to treat humans is disclosed on page 10, lines 14-15.

Second, claim 1 has been amended to recite that the allergen is selected from the group consisting of venom, animal dander, pollen, and dust mite. Recitation of these allergens is supported by originally filed claim 10.

Third, claim 1 has been amended to recite that "no more than three injections of the allergen are sufficient to desensitize the human to the allergen as assessed by sensitivity of the human to the allergen." Disclosure of three injections is found on page 11, lines 7-9. Assessment of sensitivity to allergens is disclosed on page 10, lines 22-23.

New claims 47 and 48 are presented in lieu of canceled claims 10 and 21. New claims 47 and 48 merely recite single members of the Markush group of allergens now recited in amended claim 1.

The Rejections of Claims 1-10, 14, 19-26, 45, and 46 Under 35 U.S.C. § 112, first paragraph

Claims 1-10, 14, 19-26, 45, and 46 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 10 and 21 have been canceled. Applicants respectfully traverse the rejection of claims 1-9, 14, 19, 20, 22-26, 45, and 46.

The final Office Action asserts that the rejected claims are not enabled for their full scope. In particular, the final Office Action asserts that the specification does not enable desensitization all allergens, including many of those recited in claim 10. The final Office Action also asserts that the specification provides inadequate written description many of the allergens recited in claim 10 and many of the adjuvants recited in claim 21.

To advance prosecution, Applicants have canceled claims 10 and 21 and have limited the allergens in claim 1 to venom, animal dander, pollen, and dust mites. Venom, animal dander, pollen, and dust mites are well known allergens, and preparations of these allergens for use in densensitization protocols are commercially available.

At the interview held June 24, 2003, Examiner Huynh indicated that these amendments to the claims would be sufficient to overcome the enablement and written description rejections. Applicants respectfully request that these amendments be entered and the rejections be withdrawn.

The Rejections Under 35 U.S.C. § 103(a)

The Final Office Action maintains the three rejections under 35 U.S.C. § 103(a):

- claims 1-5, 8, 9, 14, 19-26, 45, and 46 over Hong in view of Hellman, Coupey, and Zinkernagel;
- claim 10 over Hong in view of Hellman, Coupey, and Zinkernagel and further in view of Banks; and
- claims 6 and 7 over Hong in view of Hellman, Coupey, and Zinkernagel and further in view of WO 99/02183.

Claims 10 and 21 have been canceled. Applicants respectfully traverse the rejections of claims 1-8, 14, 19, 20, 22-26, 45, and 46.

Applicants do not agree that a *prima facie* case of obviousness has been made. To advance prosecution, however, at the interview held June 24, 2003 Applicants presented data that demonstrated unexpected benefits of the claimed intranodal densensitization method compared with conventional desensitization therapy. This data is contained in the declaration of Dr. Thomas Kündig that accompanies this amendment. Also at the interview, Applicants discussed with Examiners Huynh and Chan amendments to the claims that are commensurate in scope with the data presented.

Claim 1 has been amended to recite that a human is desensitized and that the allergen is either venom, animal dander, pollen, or dust mite. Claim 1 also has been amended to recite that "no more than three injections of the allergen are sufficient to desensitize the human to the allergen as assessed by sensitivity of the human to the allergen." Dr. Kündig's declaration presents data that shows an unexpected benefit of administering pollen intranodally, as recited in claim 1, compared with a conventional (subcutaneous) desensitization method. The data demonstrates that no more than three intranodal injections of the allergen are sufficient to

desensitize human patients to the allergen, as assessed by sensitivity to the allergen (via nasal provocation with the same allergen). Kündig Declaration, ¶ 7. In contrast, conventional desensitization is lengthy, lasting from 2 to 5 years, expensive, and only marginally effective. See page 6, lines 14-15 of the specification. In addition, patients who are desensitized via intranodal injections can tolerate approximately 40 times higher pollen concentrations after treatment than conventionally desensitized patients; that is, these patients already are better than what one would expect after three years of conventional treatment. Kündig Declaration, ¶ 7. According to Dr. Kündig, it was unexpected that treatment with merely three injections of 1 μg more efficiently reduces the symptom score than the extensive conventional subcutaneous regimen with 20 incremental injections up to 100 μg of the same pollen extract. Kündig Declaration, ¶ 8. Dr. Kündig's declaration also states that, based on these results, he would expect intranodal injection of venom, animal dander, and dust mites to be equally efficient when compared to conventional desensitization against these allergens.

None of the combinations of cited art teaches or suggests desensitizing a human who is allergic to venom, animal dander, pollen, or dust mite by delivering the allergen directly into a lymph node. None of the cited combinations teaches or suggests that no more than three such injections would be sufficient to desensitize the human to the allergen as assessed by sensitivity of the human to the allergen. Thus, the method of claims 1-8, 14, 19, 20, 22-26, 45, and 46 (and new claims 47 and 48) is not obvious over the cited art.

Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: July 24, 2003

By: Lisa M. Hemmendinger

Lisa M. Hemmendinger
Registration No. 42,653

1001 G Street, N.W.
Washington, D.C. 20001-4597
(202) 824-3000